DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 21, 2014

Terumo Medical Corporation
Erin Doyle
Regulatory Affairs Specialist
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Re: K142183
Trade/Device Name: Glidesheath Slender
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 21, 2014
Received: October 22, 2014

Dear Erin Doyle,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Glidesheath Slender™

Indications for Use *(Describe)*
The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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A. Submitter Information (807.92(a)(1))

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Date Prepared: November 19, 2014

B. Device Name (807.92(a)(2))

Proprietary Name:	Glidesheath Slender™
Common Name:	Introducer Sheath
Classification Name:	Introducer, Catheter
Regulation Number:	21 CFR 870.1340
Regulatory Class:	Class II
Product Code:	74 DYB
Review Panel:	Cardiovascular

C. Predicate Device (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is the current Glidesheath Slender (6Fr) which is manufactured by Ashitaka Factory of Terumo Corporation and was cleared under K122980.

D. Reason for 510(k) Submission

This premarket notification (Special 510(k)) is being submitted to extend the current Glidesheath Slender (6Fr) product line to include the 5Fr and 7Fr sizes. This is a modification to the Glidesheath Slender (6Fr) (K122980) introducer sheath manufactured by Ashitaka Factory of Terumo Corporation.

E. Device Description (807.92(a)(4))

Principle of Operation Technology
The Glidesheath Slender (GSS) (5Fr & 7Fr) submitted in this 510(k) and the GSS (6Fr) cleared under K122980 are operated manually or by a manual process.

Design/Construction
Both the predicate Glidesheath Slender 6Fr (GSS 6Fr) and the modified Glidesheath Slender 5Fr & 7Fr (GSS 5Fr & 7Fr) consist of an introducer sheath and a dilator which are packaged together with an entry needle, mini guide wire and guide wire inserter. The GSS devices (all sheath sizes) are used to facilitate placing a catheter through the skin into the radial artery. The sheath and dilator contain bismuth, making these devices visible under fluoroscopy. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel.

The entry needle (cannula) is used to gain access to the radial artery for placement of the mini guide wire. The entry needle is offered in two versions, either a stainless steel entry needle or a Surflo IV catheter (K891087).

The mini guide wire is used for placement of the sheath and dilator into the radial artery. The mini guide wire is offered in two versions, either a stainless steel (spring coil) model or a polyurethane (nitinol core) plastic model.

The mini guide wire is inserted through a cannula placed in the patient's blood vessel. A guide wire inserter is provided to assist in insertion of the mini guide wire into the cannula. Following guide wire insertion, the cannula is removed and the sheath and dilator are then inserted over the mini guide wire and into the blood vessel. The mini guide wire is then withdrawn from the vessel. The dilator maintains the integrity of the sheath and dilates the blood vessel during insertion. Once the sheath is situated in the vessel, the dilator is removed and an appropriate catheter can then be inserted through the sheath.

The entry needle, the mini guide wire and the guide wire inserter are packaged with the GSS in an individual package prior to sterilization. With the exception of the Surflo IV catheter, which is cleared under K891087, accessories provided in the GSS kit are not offered for individual sale.

Materials

The materials for all GSS sheath sizes including the modified GSS (5Fr & 7Fr) and predicate GSS (6Fr) are provided in **Table 5.1** below.

Table 5.1: GSS Materials (All Sheath Sizes)

GSS Component		Material
Sheath	Tube	Ethylene-Tetrafluoroethylene (ETFE) copolymer, Bismuth Trioxide
	Hydrophilic Coating	Dimethyl acrylamide-glycidyl methacrylate copolymer
	Housing	Polypropylene
	Caulking Pin	Stainless Steel
	Cap	Polypropylene
	Valve	Silicone Rubber
	Sheath Support	Styrene-ethylene-butylene-styrene block copolymer
	Side Tube	Polybutadiene
	3-Way Stopcock	Polyethylene, Polypropylene, Polycarbonate
Dilator	Tube	Polypropylene, Bismuth subcarbonate
	Hub	Polypropylene
	Caulking Pin	Stainless Steel
Guide Wire Plastic Type		Nickel-Titanium alloy, Tungsten, Polyurethane
Guide Wire Spring Type		Stainless Steel
Guide wire inserter		Polyethylene
Stainless steel entry needle	Cannula	Stainless Steel
	Hub	Polycarbonate
Surflo IV Catheter	Catheter tube	Ethylene-Tetrafluoroethylene (ETFE) copolymer, Barium sulfate
	Hub	Polypropylene
	Caulking Pin	Stainless Steel
	Filter Cap	Polystyrene, Polyester-Chlorinated polyvinyl chloride
	Adapter	Polypropylene
	Needle Cannula	Stainless Steel
	Needle Hub	Polycarbonate

Specifications
Table 5.2 below provides the device specifications for the modified GSS 5Fr & 7Fr and the predicate GSS (6Fr).

Table 5.2: Glidesheath Slender Device Specifications

Component	Specification	GSS (6Fr) - (Predicate)	GSS (5Fr) - (Modified)	GSS (7Fr) - (Modified)
Sheath	Size	6Fr	5Fr	7Fr
	Length (cm)	10, 16		
	Hydrophilic coating (cm)	10, 16 (entire length of sheath)		
Dilator	Length (cm)	15.5, 21.5		
Guide Wire Plastic Type	Outer Diameter (inch)	0.018, 0.021, 0.025, 0.035		
	Length (cm)	45, 80		
Guide Wire Spring Type (Stainless Steel)	Outer Diameter (inch)	0.018, 0.021, 0.025, 0.035		
	Length (cm)	45, 80		
Surflo IV Catheter	Size (Gauge)	18, 20, 22		
	Length (mm)	25, 32, 51, 64 (1" , 1 1/4" , 2" , 2 1/2")		
Stainless Steel Entry Needle	Size (Gauge)	20, 21		
	Length (mm)	35 (1 2/5")		

F. Intended Use (807.92(a)(5))

The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.

Note: This intended use is identical to the predicate device, Glidesheath Slender (K122980).

G. Substantial Equivalence Comparison (807.92(a)(6))

The Glidesheath Slender (5Fr & 7Fr), subject of this Special 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the Glidesheath Slender (6Fr) cleared under K122980, manufactured by Ashitaka Factory of Terumo Corporation, Japan.

A comparison of the technological characteristics is summarized in **Table 5.3** below.

Table 5.3: Summary of Comparative Information between the Modified GSS (5Fr & 7Fr) and the Predicate Device GSS (6Fr)

Device Characteristic		**Predicate GSS (6Fr) – K122980**	**Modified GSS (5Fr & 7Fr)**
Trade Name		Glidesheath Slender™	same
Manufacturer		Ashitaka Factory of Terumo Corporation	same
Intended Use		The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.	same
Principle of Operation / Technology		Manual	same
Device Components		1. Sheath 2. Dilator 3. Plastic or Stainless Steel Guide Wire 4. Stainless Steel Entry Needle or Surflo IV Catheter	same
Available Sheath Sizes		6 Fr	5Fr & 7Fr
Available Sheath Lengths		Effective Length: 100mm, 160mm	same
Sheath Radiopacity		Yes	same
Dilator Radiopacity		Yes	same
Material	Sheath	ETFE copolymer, Bismuth Trioxide, Dimethyl acrylamide-glycidyl methacrylate copolymer, Polypropylene, Stainless Steel, Silicone Rubber, Styrene-ethylene-butylene-styrene block copolymer, Polybutadiene, Polycarbonate, Polyethylene	same
	Dilator	Polypropylene,Bismuth subcarbonate, Stainless Steel	same
	Guide wire plastic type	Nickel-Titanium alloy, Tungsten, Polyurethane	same
	Guide wire spring type	Stainless Steel	same
	Guide wire inserter	Polyethylene	same
	Stainless steel entry needle	Stainless Steel, Polycarbonate	same
	Surflo IV catheter	ETFE copolymer, Barium sulfate, Polypropylene, Stainless Steel, Polystyrene, Polyester-Chlorinated polyvinyl chloride, Polycarbonate	same

Device Characteristic	Predicate GSS (6Fr) – K122980	Modified GSS (5Fr & 7Fr)
Sheath Performance	• Meets ISO 11070: Sterile single-use intravascular catheter introducers • M Coating (Hydrophilic coating) Particulate Evaluation per FDA PTCA Guidance Test[1] / USP788 • Meets following internal standards: o Catheter Insertion and Removal Resistance o Penetration Resistance o External Surface Sliding Performance o Hydrophilic coating (M Coating) Separation Resistance	same
Packaging Material	Polyester-polyethylene laminated film and paper	same
Sterilization Method	Ethylene Oxide	same
Shelf - life	30months	same

H. Non Clinical Tests (807.92(b)(1))

Performance
Performance testing was conducted to ensure safety and effectiveness of the modified GSS (5Fr & 7Fr) device throughout the shelf-life, verify conformity to applicable ISO and internal standards and acceptance criteria, and demonstrate substantial equivalence to the predicate device.

No new issues of safety and effectiveness were raised with the testing performed and results were within the predetermined acceptance criteria. The performance of the modified GSS (5Fr & 7Fr) is substantially equivalent to that of the predicate GSS (6Fr) device and is safe and effective for its intended use.

A list of the performance tests that were conducted is provided in the **Table 5.4** below.

[1] *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (2010)*

Table 5.4 GSS 5Fr & 7Fr Verification Tests

Test	Standard
Sheath	
Surface	ISO 11070: Sec. 4.3
Corrosion Resistance	ISO 11070: Sec. 4.4
Radiodetectability	ISO 11070: Sec.4.5
Size Designation (Dimensional Verification)	ISO 11070: Sec. 7.2
Freedom from Leakage from Sheath Introducer	ISO 11070: Sec. 7.3
Freedom from Leakage through Haemostasis Valve	ISO 11070: Sec. 7.4
Force at Break (sheath)	ISO 11070: Sec. 7.6
Force at Break (sheath to hub)	ISO 11070: Sec. 7.6
Sheath to Dilator Fit	ISO 11070: Annex A.1
Rollback Test	ISO 11070: Annex A.1
Puncture model test	ISO 11070: Annex A.1
Flexibility (Kink Angle)	ISO 11070: Annex A.1
Flexibility (Radius of Curvature)	ISO 11070: Annex A.1
Catheter Insertion and Removal Resistance	Internal Standard
Penetration Resistance	Internal Standard
External Surface Sliding Performance	Internal Standard
Hydrophilic coating (M Coating) Separation Resistance	Internal Standard
Hydrophilic coating (M Coating) Particulate Evaluation	FDA Guidance[2] USP 788
Dilator	
Surface	ISO 11070: Sec. 4.3
Size Designation (Dimensional Verification)	ISO 11070: Sec. 9.2
Conical Fitting	ISO 11070: Sec 9.3.2 ISO594-1
Strength of Union between Hub and Dilator	ISO 11070: Sec 9.3.3

[2] *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*

Biocompatibility

Biocompatibility of the modified GSS (5Fr & 7Fr) was evaluated based upon ISO 10993-1: 2009. The modified GSS (5Fr & 7Fr) including Sheath, Dilator, Guidewire, and Entry needle are classified as Externally Communicating Devices, Circulating Blood, Limited Contact (<24 hrs). This is the same classification as the predicate Glidesheath Slender (6Fr) (K122980).

All of the modified GSS (5Fr & 7Fr) materials are the same as the predicate GSS (6Fr) (K122980) and/or other currently marketed Terumo devices including the Glidesheath (5Fr) (K082644) and the Radiofocus Introducer II Kit (7Fr) (K954234). These devices have the same intended use, body contact and contact duration classification based on ISO10993-1: 2009. The Glidesheath and Radiofocus Introducer product lines have a demonstrated history of safe and effective use.

Additionally, biocompatibility testing was conducted in accordance with the FDA General Program memorandum #G95-1(5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". Samples tested were final, sterilized, whole finished good devices (including Sheath, Dilator, Guidewire, Guidewire Inserter, and Entry needle). Testing was conducted in accordance with 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies).

Physiochemical Profile (Physicochemical and FT-IR Analysis) testing was also conducted by Terumo Corporation per USP <661> Containers-Plastics: Physiochemical Tests. Testing demonstrated that the physiochemical properties of the subject GSS device do not change throughout its shelf life, and, therefore, remain biocompatible.

All test results met the requirements of applicable standards. A list of biocompatibility tests conducted are summarized **Table 5.5** on the following page.

Table 5.5: Glidesheath Slender – Biocompatibility Testing Summary

Test / Method / Standard	
Cytotoxicity: L929 MEM Elution Test - ISO 10993-5: 2009	
Sensitization: Kligman Maximization Test - ISO 10993-10: 2010	
Irritation/ Intracutaneous Reactivity: Intracutaneous Injection Test - ISO 10993-10: 2010	
Acute Systemic Toxicity: Systemic Injection Test - ISO 10993-11: 2006	
Pyrogenicity: Rabbit Pyrogen Test (Material Mediated) - ISO 10993-11: 2006	
Hemocompatibility	**Hemolysis:** Hemolysis Complete (Direct and Indirect) - ASTM F 756: 2008
	Complement Activity: Complement Activation Assay Direct Contact - ISO 10993-4: 2002/A1:2006
	Thrombosis: Thrombogenicity Study in Dogs- ISO 10993-4: 2002/A1:2006
Physiochemical Profile	**Physicochemical USP <661>**
	FT-IR USP <661>

We conclude therefore that the modified GSS (5Fr & 7Fr) is biocompatible for its intended use.

Sterilization

The sterilization conditions have been validated according to ANSI / AAMI / ISO 11135-1, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices,* to provide a Sterility Assurance Level (SAL) of 10^{-6}. The validation is on file and available upon request.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on ISO 10993-7, *Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals*. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

Pyrogen Testing
The Glidesheath Slender is certified to be non-pyrogenic in the unopened and undamaged package. Limulus Amebocyte Lysate (LAL) (Photometric Quantitative Method) testing is performed on each lot of product in accordance to the United States Pharmacopoeia (USP) <85> Bacterial Endotoxins Test. Validation was performed in accordance with FDA published "Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers; June 2012".

Risk Analysis
A Product Risk Analysis was conducted in accordance with ISO 14971: 2007, taking into account the modifications to the previous device, and it was determined that there were no new issues of safety or effectiveness.

I. Clinical Tests (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. Conclusion (807.92(b)(3))

The proposed GSS (5Fr & 7Fr) is substantially equivalent in intended use, principles of operation, design features, materials, performance and fundamental scientific technology when compared to the predicate GSS (6Fr) (K122980). Verification testing was conducted and demonstrated that the modified device meets the design inputs and meets the same or equivalent requirements as the predicate GSS (6Fr) for both ISO 11070 and internal standards. The differences between the predicate and proposed devices do not raise any new issues regarding safety and effectiveness. Therefore, the GSS (5Fr & 7Fr) is considered substantially equivalent to the predicate device.